

REMARKS

With entry of this amendment, Claims 19-38 are pending. Claims 19 and 30 have been amended. No new matter has been added by these amendments.

35 U.S.C. §103(a)

Claims 19-38 are rejected under 35 U.S.C. §103(a) as being unpatentable over Jain *et al.* (EP 812,587). The Office Action states that Jain *et al.* teaches a non-staining composition of nimesulide, which contains monoglycerides, such as glycerol monooleate, in an amount ranging from 0.5% to 12% by weight and that it is well known in the art that nimesulide possesses both anti-inflammatory and analgesic properties. Applicants traverse this rejection.

Jain *et al.* teaches that “the layers of the skin are different in nature, some are hydrophilic while some are lipophilic. Accordingly, any drug which is used transdermally must possess both hydrophilic and lipophilic properties. Nimesulide ...is a highly hydrophobic drug and consequently it is considered a poor candidate for transdermal absorption.” (pg. 2, lines 12-17). Jain *et al.* therefore teaches away from the present invention as currently claimed. In order to circumvent the absorption problem, Jain *et al.* requires the use of a percutaneous enhancer to transport the drug through the transdermal route. Additionally, Jain *et al.* states that “water is required for the composition” (page 3, line 35).

The composition described by the present invention is anhydrous in nature. Jain *et al.* requires water and surfactants to form emulsions that have the correct hydrophilic and lipophilic balance. Because hydrophobic components that are mixed with water are not miscible, surfactants are utilized to reduce the surface tensions and to create stable dispersions. The glycerol monooleate in Jain *et al.*

functions as a surfactant, not as a solvent phase as required in the present invention. The composition in Jain *et al.*, which teaches the use of surfactants and water to transport the nimesulide does not teach, suggest or disclose the present invention as currently claimed. Applicants respectfully request the Examiner withdraw this rejection.

35 U.S.C. §103(a)

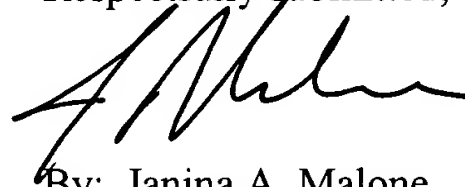
Claims 19-25 and 30-38 are rejected under 35 U.S.C. §103(a) over Kruse *et al.* (U.S. Patent No. 5,744,458). The Office Action states that Kruse *et al.* teaches a topical composition which contains nimesulide and glyceryl mono-fatty acid esters. Applicants traverse this rejection.

Kruse *et al.* teaches a lotion containing an effective concentration of one or more of the compounds with an emollient, and “the balance water, a suitable buffer, a C₂ or C₃ alcohol, or a mixture of water of the buffer and the alcohol.” (Kruse *et al.*, column 114, lines 35-45). As argued above, the present invention is essentially anhydrous in nature. The requirement of water in Kruse *et al.* to create the lotion therefore does not teach, suggest, or disclose the present invention as currently claimed. Applicants request this rejection be withdrawn.

Application No. 09/762,630
Amendment dated June 3, 2003
Response to Office Action dated March 27, 2003

Applicants respectfully submit that this is a complete response to the Office Action dated March 27, 2003 and that Claims 19-38 are patentable. Early and favorable consideration is earnestly solicited. If the Examiner believes there are other issues that can be resolved by telephone interview, or that there are any informalities remaining in the application which may be corrected by Examiner's Amendment, a telephone call to the undersigned attorney at (404) 815-6500 is respectfully solicited.

Respectfully submitted,



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